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PATTON BOGGS LLP
8484 WESTPARK DRIVE
SUITE 900
MCLEAN, VA 22102

EXAMINER	
HELM, CARALYNNE E	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,643	CASTAN ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 1 page.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "at least one hydrophobic compound different from A" in the section 2B. Since the claim states that only one family of compositions (A, B, or C) would be selected from for the film coating, no other reference to "A" exists. In addition, claim 1 also recites in section 1A "...film-forming polymer (P1) insoluble in the tract fluids...." but no previous reference to or description of a "tract" is present in the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 recites the limitation "...once the two solids and liquid phases... ". No prior reference was made to two solid phases. There is insufficient antecedent basis for this limitation in the claim. Although the "two phases" recited could imply the liquid and solid phases, the current recitation is confusing as to what is truly intended by the applicant.

Claims 1, 2, 4-6, 8-12, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1, 4, 5, and 9-11 recite a broad range and also recite an additional range which is the narrower statement of the range. For example, claim 1 recites under section 1A "...at least one film forming polymer...present in an amount of 50 to 90 percent...", then also recites this same component present at the narrower range of "50 to 80 percent". In addition, claims 1, 2, 6, 8, 12, and 15 recite a broad limitation and also recite an additional limitation which is the narrower statement of the limitation For example, claim 1 recites under section 1B "...at least one hydrophilic polymer carrying groups ionized at neutral pH...", then also recites this same component is "preferably selected from cellulose derivatives". These embedded limitations within limitations render the claim indefinite.

Carvais also teaches that the invention is suitable fro drugs that run the spectrum from water insoluble to water soluble (see page 1 line 33-page 2 line 5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 5-12, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carvais (U.S. Patent No. 4,902,513) in view of Paillard et al. (U.S. Patent No. 6,699,506).

Carvais teaches a sustained release liquid oral suspension that comprises a suspension with microcapsules of a drug suspended in a saturated solution of the drug, where dissolution of the microcapsules maintains the saturation level of drug in solution (see column 1 lines 26-38; instant claims 1, 5-8, and 19). Initially, none of the drug in the microcapsule contributes to that in the liquid phase, but over time as drug is removed from the liquid, the drug from the

microcapsules brings the concentration in the liquid back to the level of saturation. This liquid phase is taught to be either non aqueous or aqueous (see column 1 lines 18-19 and 21-23). Carvais also teaches that the invention is suitable for drugs that run the spectrum from water insoluble to water soluble (see column 1 lines 16-25). In particular Carvais teaches the use of theophylline as the drug in the invention (see page 2 lines 25-28; instant claims 1 and 17-18). Beyond the drug to be included, Carvais does not teach a particular microcapsule composition.

Paillard et al. teach a controlled release microparticulate drug form oral delivery (see column 1 lines 8-10; instant claim 1). Paillard et al. also teach that coatings have been used to control the release of drug from minigranular preparations (see column 3 lines 6-15; instant claim 1). The taught minispheres or minigranules (microcapsules) have a coating composed of several ingredients including a film-forming polymer insoluble in water. Methacrylic copolymers of the poly(ethyl acrylate, methyl methacrylate) type, alkyl celluloses and ethyl cellulose, where ethyl cellulose is particularly exemplified, are taught as film-forming polymers (see column 6 lines 45-46, 49-55, column 7 lines 11-19; instant claims 1-2). Within the ethyl cellulose coating preparations, Paillard et al. also teach the presence of polyvinylpyrrolidone as a pore-former, as well as a plasticizer; here triethyl citrate is preferred while glycerols and castor oil are taught as additional envisioned varieties of plasticizers (see column 7 lines 20-35 and 41-42; instant claim 1-2). In addition, Paillard et al. teach that minigranules are coated at 4%-12% (by weight) and have a size between 750 and 1100 μm (see column 3 lines 58-65; instant claims 9 and 10). Since sustained release of drug is a main goal of the Carvais invention, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Paillard et al. with Carvais. This combination would result in a liquid suspension of theophylline where the liquid phase was saturated with theophylline and the solid phase was coated microparticles containing theophylline. In addition, since the combined references teach

an embodiment with the same drug and coating components as that taught by the applicant, absent any evidence to the contrary, the function claimed by the applicant would also be present in the invention of the prior art (see instant specification example 2). Thus, the limitations of claims 11 and 12 are also taught by Carvais modified by Paillard et al. Therefore, claims 1-2, 5-12, and 17-19 are obvious over Carvais in view of Paillard et al.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carvais in view of Meadows et al. (U.S. PGPub No. 2003/0099711).

As discussed above, Carvais teaches a saturated suspension of theophylline that also contains microcapsules of theophylline, but does not teach detail about the other components present in the microcapsule, beyond the drug (see ***Claim Rejections - 35 USC § 103*** for claims 1-2, 5-12, and 17-19). Meadows et al. teach small drug complexes for oral delivery that provide sustained release of the contained drug (see paragraph 1 lines 1-5). Meadows et al. go on to discuss various coating configurations used in their invention that include single layers of barrier or enteric coatings separately as well as together (see paragraphs 62-67; instant claim 3). Meadows et al. further teach the components of these layers where the barrier is taught to contain ethyl cellulose and a plasticizer such as castor oil or vegetable oil (see paragraph 38, paragraph 40 lines 6-8, 16-17, 22-25 and paragraph 41 lines 1 and 6-7; instant claims 1-2). Further, Meadows et al. also teach that when in liquid suspension the coated drug particles are present at a level between about 1% and about 50% by weight thus the liquid is present at a level between about 50% and about 99% (see paragraph 55 lines 1-4; instant claim 4). It would have been obvious to one of skill in that art at the time the invention was made to use the coating scheme as well as the particle composition of Meadows et al. to produce the sustained

release theophylline suspension taught by Carvais. Therefore claims 1-4 are obvious over Carvais in view of Meadows et al.

Claims 1-2, 13-16, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carvais in view of Ulrich et al. (US PGPub No. 2002/0197327).

As discussed above, Carvais teaches a saturated suspension of theophylline that also contains microcapsules of theophylline, but does not teach detail about the other components present in the microcapsule (see ***Claim Rejections - 35 USC § 103*** for claims 1-2, 5-12, and 17). Ulrich et al. teach an acidic liquid suspension of coated drug (see paragraphs 18 and 27; instant claim 13) Ulrich et al. further teach the components present in the coating include an acrylic derivative, and additives such as triethyl citrate and polyvinylpyrrolidone (see paragraphs 18 and 32; instant claims 1-2). It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to use the coating and acidic suspending medium of Ulrich et al. to produce the theophylline suspension of Carvais that is delivered in the intestine. Ulrich et al. also teach the inclusion of acidifying agents (drug solubility modifiers), coloring agents, sweeteners, and preservatives in the composition with the coated drug (see paragraph 34; instant claims 15-16). In addition, Ulrich et al. also teach the inclusion of microcrystalline and carboxymethyl cellulose, which can both server the function of rheology modifiers, along with the coated drug (see example 6; instant claim 14). Further, Ulrich teach that the dry powder form of the coated drug can be provided for later reconstitution with a liquid vehicle (see paragraph 34 line 7-9; instant claim 20). It again would have been obvious at the time the invention was made to use the teachings of Ulrich et al. in the invention of Carvais. Thus, claims 1-2, 13-16 and 20 are obvious over Carvais in view of Ulrich et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 4-10, 15, and 17-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-17 and 19-31 of copending Application No. 10/522,252 in view of Carvais. Both the instant application and application 10/522,252 teach an oral suspension of a drug (both teach many of the same classes and particular drugs, including naproxen, ganciclovir, and morophine) containing microcapsules coated at 1% to 50% (by mass) with a film comprising a film forming polymer insoluble in gastrointestinal tract fluid, a water soluble polymer and a plasticizer. Both also teach that the microcapsules are less then 1000 μm in size and are present within the suspension at a level between 5% and 70%. In addition, both applications also teach the presence of a solubilizing agent in the liquid phase. Application 10/522,252 does not teach that the liquid phase of the suspension is saturated with the drug. Carvais teaches a suspension of drug that contains microcapsules of the drug and whose liquid phase is saturated with the drug. One of

ordinary skill in the art at the time the invention was made would have found it obvious to use the teachings of Carvais to modify the invention of application 10/522,252 to practice the instant invention to have a product capable of instant as well as prolonged drug delivery.

Claims 1-3, 5-10, and 17-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7-8, and 11-12 of copending Application No. 10/492,129 in view of Carvais. Both the instant application and application 10/492,129 teach an oral composition of drug (both teach many of the same classes and particular drugs including naproxen, ganciclovir, and morophine) containing microcapsules coated at 1% to 50% (by mass) with a film comprising a hydrophilic polymer carrying groups that are ionized as neutral pH and a hydrophobic polymer. Both also teach that the microcapsules are less then 1000 μm in size. Application 10/492,129 does not teach a suspension form where the liquid phase is saturated with the drug. Carvais teaches a suspension of a drug that contains microcapsules of the drug and whose liquid phase is saturated with the drug. Since suspensions are a well known forms for the oral delivery of microcapsules, one of ordinary skill in the art at the time the invention was made would have found it obvious to use the teachings of Carvais to modify the invention of application 10/492,129 to practice the instant invention so as to have a liquid product capable of instant as well as prolonged drug delivery.

Claims 1-3, 5-10, 17, and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 11-24, 26, 31, 41-50, 58-76, 89-91, 99-101, and 113 of copending Application No. 11/707,034 in view of Carvais. Both the instant application and application 11/707,034 teach an oral suspension of a drug containing

microcapsules coated with a film comprising one of same three compositions 1) a film forming polymer insoluble in gastrointestinal tract fluid, a water soluble polymer, a plasticizer, a surfactant and/or a lubricant, 2) a water insoluble cellulose derivative, nitrogen-containing polymer, plasticizer, and surfactant, and 3) a hydrophilic polymer carrying groups that are ionized at neutral pH and a hydrophobic compound. Both also teach many of the same specific ingredients that fall into the categories of components in the film coating. Both also teach that the microcapsules are less then 1000 μm as well as the inclusion of anti-viral drugs. Application 11/707,034 does not teach that the liquid phase of the suspension is saturated with the same anti-viral drug contained in the microcapsules. Carvais teaches an oral suspension of drug that contains microcapsules of the drug and whose liquid phase is saturated with the drug. One of ordinary skill in the art at the time the invention was made would have found it obvious to use the teachings of Carvais to modify the invention of application 10/522,252 to practice the instant invention in order to have a product capable of instant as well as prolonged drug delivery.

The applicant has a large number of additional copending applications (see table below) that claims subject matter strikingly similar to those used here against the instant applicant (microparticulate composition with the same film coating compositions that deliver the same if obvious modifications of the drug(s) I the instant application). In view of the teachings of Carvais most, if not all of these applications would result in provisional rejections against the instant claims. It is incumbent upon the applicant to delineate the differences between the claimed materials and the copending applications in view of the Carvais or file terminal disclaimers as necessary.

Copending Applications with Conflicting Claims

10/478420	11/449675
10/519641	11/648605
10/580023	11/651577
10/580035	11/707054
10/580037	11/723553
10/826690	11/791466
10/996780	11/802610
10/997836	11/883935
11/358047	11/884534
11/439247	11/884549
11/439431	11/920741

These are a provisional obviousness-type double patenting rejection.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Caralynne Helm
Examiner
Art Unit 4173

CH

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600